

**Notice of Allowability**

Application No.

10/646,980

Examiner

James H. Alstrum-Acevedo

Applicant(s)

CHU ET AL.

Art Unit

1616

**-- The MAILING DATE of this communication appears on the cover sheet with the correspondence address--**

All claims being allowable, PROSECUTION ON THE MERITS IS (OR REMAINS) CLOSED in this application. If not included herewith (or previously mailed), a Notice of Allowance (PTOL-85) or other appropriate communication will be mailed in due course. **THIS NOTICE OF ALLOWABILITY IS NOT A GRANT OF PATENT RIGHTS.** This application is subject to withdrawal from issue at the initiative of the Office or upon petition by the applicant. See 37 CFR 1.313 and MPEP 1308.

1. ☒ This communication is responsive to after final amendments, arguments, and terminal disclaimer filed on 9/28/06.
2. ☒ The allowed claim(s) is/are 20-24, 27-34, and 37-39.
3. ☐ Acknowledgment is made of a claim for foreign priority under 35 U.S.C. § 119(a)-(d) or (f).
- a) ☐ All b) ☐ Some\* c) ☐ None of the:
1. ☐ Certified copies of the priority documents have been received.
2. ☐ Certified copies of the priority documents have been received in Application No. \_\_\_\_\_.
3. ☐ Copies of the certified copies of the priority documents have been received in this national stage application from the International Bureau (PCT Rule 17.2(a)).

\* Certified copies not received: \_\_\_\_\_.

Applicant has THREE MONTHS FROM THE "MAILING DATE" of this communication to file a reply complying with the requirements noted below. Failure to timely comply will result in ABANDONMENT of this application.

**THIS THREE-MONTH PERIOD IS NOT EXTENDABLE.**

4. ☐ A SUBSTITUTE OATH OR DECLARATION must be submitted. Note the attached EXAMINER'S AMENDMENT or NOTICE OF INFORMAL PATENT APPLICATION (PTO-152) which gives reason(s) why the oath or declaration is deficient.
5. ☐ CORRECTED DRAWINGS ( as "replacement sheets") must be submitted.
- (a) ☐ including changes required by the Notice of Draftsperson's Patent Drawing Review ( PTO-948) attached
- 1) ☐ hereto or 2) ☐ to Paper No./Mail Date \_\_\_\_\_.
- (b) ☐ including changes required by the attached Examiner's Amendment / Comment or in the Office action of Paper No./Mail Date \_\_\_\_\_.
- Identifying indicia such as the application number (see 37 CFR 1.84(c)) should be written on the drawings in the front (not the back) of each sheet. Replacement sheet(s) should be labeled as such in the header according to 37 CFR 1.121(d).
6. ☐ DEPOSIT OF and/or INFORMATION about the deposit of BIOLOGICAL MATERIAL must be submitted. Note the attached Examiner's comment regarding REQUIREMENT FOR THE DEPOSIT OF BIOLOGICAL MATERIAL.

**Attachment(s)**

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|--|---|
| 1. <input type="checkbox"/> Notice of References Cited (PTO-892)   | 5. <input type="checkbox"/> Notice of Informal Patent Application                                 |
| 2. <input type="checkbox"/> Notice of Draftsperson's Patent Drawing Review (PTO-948)                       | 6. <input checked="" type="checkbox"/> Interview Summary (PTO-413),<br>Paper No./Mail Date _____. |
| 3. <input type="checkbox"/> Information Disclosure Statements (PTO/SB/08),<br>Paper No./Mail Date _____    | 7. <input checked="" type="checkbox"/> Examiner's Amendment/Comment                               |
| 4. <input type="checkbox"/> Examiner's Comment Regarding Requirement for Deposit<br>of Biological Material | 8. <input checked="" type="checkbox"/> Examiner's Statement of Reasons for Allowance              |
|  | 9. <input type="checkbox"/> Other _____.  |

*Examiner's Amendment*

An examiner's amendment to the record appears below. Should the changes and/or additions be unacceptable to applicant, an amendment may be filed as provided by 37 CFR 1.312. To ensure consideration of such an amendment, it MUST be submitted no later than the payment of the issue fee.

Authorization for this examiner's amendment was given in a telephone interview with Mr. Henry D. Coleman, Esq. on October 20, 2006 and October 25, 2006.

The application has been amended as follows:

- (1) In claim 20, line 3, insert the word "and" before the word "lymphoma."
- (2) In claim 20, line 3; insert the word "cancer" after the word "lymphoma."
- (3) In claim 20, line 3, delete the word "--and--" after the word "lymphoma."
- (4) In claim 22, line 2, delete "--\_--" between the words "cell" and "lung."
- (5) In claim 30, line 5, insert the word "and" before the word "lymphoma."
- (6) In claim 30, line 5, delete the word "--and--" after the word "lymphoma."
- (7) In claim 30, beginning on line 2 after the word "of" and up to the word "non-small" on line 4 delete the following: "--lung cancer, colorectal cancer, breast cancer, prostate cancer, bladder cancer, pancreatic cancer, ovarian cancer, uterine cancer, leukemia, cns cancer, melanoma, renal cancer, lymphoma and head and neck--."
- (8) In claim 32, line 1, insert the words "non-small cell" after the word "is."
- (9) In claim 39, line 2, delete "--myeloid--" and replace with "lymphoblastic."
- (10) Amend claims 21-24 and 27-29 to depend from claim 1.
- (11) Amend claims 31-34 and 37-39 to depend from claim 9.

(12) In claim 20, line 4, insert the phrase "in need thereof" after the word "animal".

(13) In claim 30, line 6, insert the phrase "in need thereof" after the word "human".

(14) In claim 20, line 6 delete ", said cancer being sensitive to treatment with said compound".

(15) In claim 30, line 9 delete ", said cancer being sensitive to treatment with said compound".

(16) In claim 28, line 2, insert the word "cancer" after "lymphoma".

(17) In claim 38, line 2, insert the word "cancer" after "lymphoma".

### ***REASONS FOR ALLOWANCE***

The following is an examiner's statement of reasons for allowance: (1) Applicant's filing of a terminal disclaimer on October 16, 2006 over U.S. Patent No. 5,817,667 and amendments to the claims have overcome the rejections of record; and (2) Applicant's specification enables the treatment of non-small cell lung cancer, colon cancer, breast cancer, prostate cancer, ovarian cancer, leukemia (e.g. acute lymphoblastic leukemia), CNS cancer, melanoma, renal cancer, and lymphoma cancer, as evidenced by the  $\log_{10}GI_{50}$  (i.e. log of the concentration of drug required for 50% tumor growth inhibition),  $\log_{10}TGI$  (i.e. log of the concentration of drug required for total tumor growth inhibition), and  $ID_{50}$  (drug concentration exhibiting inhibition of 50% tumor growth) (pg. 34 only) data tabulated on pages 28-29 and 34 and explained in the specification. The terminal disclaimer was approved on October 21, 2006.

Any comments considered necessary by applicant must be submitted no later than the payment of the issue fee and, to avoid processing delays, should preferably accompany the issue

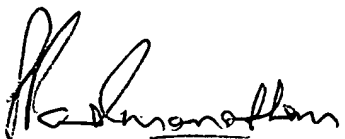
fee. Such submissions should be clearly labeled "Comments on Statement of Reasons for Allowance."

Any inquiry concerning this communication or earlier communications from the examiner should be directed to James H. Alstrum-Acevedo whose telephone number is (571) 272-5548. The examiner can normally be reached on M-F, 9:00-6:30, with every other Friday off.

If attempts to reach the examiner by telephone are unsuccessful, the examiner's supervisor, Johann Richter can be reached on (571) 272-0646. The fax phone number for the organization where this application or proceeding is assigned is 571-273-8300.

Information regarding the status of an application may be obtained from the Patent Application Information Retrieval (PAIR) system. Status information for published applications may be obtained from either Private PAIR or Public PAIR. Status information for unpublished applications is available through Private PAIR only. For more information about the PAIR system, see <http://pair-direct.uspto.gov>. Should you have questions on access to the Private PAIR system, contact the Electronic Business Center (EBC) at 866-217-9197 (toll-free).

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